HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1162B

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

WARNING LETTER

February 5, 1997

Cin 97-214

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bruce Lauer
Director of Radiology
Jewish Hospital System, Inc.- MOBILE
3200 Burnet Ave.
Cincinnati, OH 45229

Facility Inspection I.D.#T00057T67
Facility Certificate # 208173

Dear Mr. Lauer:

Your facility (mobile operation) was inspected on January 22, 1997 by a representative from the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> Your records indicate that there was no medical physicist survey performed for the x-ray processing system at the mammography remote site ([redacted]

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

The other items listed in your January 22, 1997 inspection report identified as Level 3 should also be corrected. We will verify correction of these items during our next inspection and you are not required to address this in your written response.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct the Level 1 deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513)684-3501, extension 138.

Sincerely yours,

John R. Marzilli
District Director
Cincinnati District Office

c.
RTBolen